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Filing Date	July 31, 2001
First Named Inventor	Massaro, et al.
Art Unit	1625
Examiner Name	D. Margaret Seaman
Attorney Docket Number	17293 DIV

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
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Date	Oct 27, 2006	Reg. No.	28,675

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Signature	Toni Whyte		
Typed or printed name	Toni Whyte	Date	10.27.06

17293 DIV

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	
	Examiner: D. Margaret Seaman
Massaro et al.	
	Art Unit: 1625
Serial No.: 09/919,195	
Filed: July 31, 2001	
For: METHODS AND COMPOSITIONS FOR THE TREATMENT AND PREVENTION OF LUNG DISEASE	

Certificate of Mailing

I hereby certify that this correspondence is being deposited on 10.27.06 with the United States Postal Service as first class mail in an envelope addressed to Mail Stop Appeal Brief, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Toni Whyte

Date: October 27, 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS

APPELLANT'S REPLY TO EXAMINER'S ANSWER PURSUANT TO CONSOLIDATED PATENT RULES § 41.41

Honorable Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

In accordance with Consolidated Patent Rules 41.41, Appellant hereby submits its Reply to the Examiner's Answer, which is dated September 6, 2006.

REASONED STATEMENT AGAINST EXAMINER'S ANSWER THAT MAINTAINS THE REJECTION PURSUANT TO 35 U.S.C. Sections 112, first paragraph, AND Section 102(b)

Argument Against Rejection For Alleged Anticipation

Applicant respectfully disagrees with the Examiner's statement regarding the grouping of claims (page 3, paragraph 7 of the Examiner's Answer), wherein the Examiner asserts that all claims (Claim 13 – 28) stand or fall together because Appellant's brief does not include a statement and support for the statement that certain claims, or groups of claims, require independent evaluation for patentability under 35 U.S. C. Section 102(b). Specifically, in the mailing of September 6, 2006, the Examiner also wrote that applicant's previously submitted reply brief of 6/01/2005 "contains arguments that the claims do not stand or fall together, but the appeal brief of *2/2/2006*[1] [sic] does not contain a statement as to the claims standing or falling together." These assertions by the Examiner are in error. On **page 8 of the Appeal Brief** (original and amended) applicant argues that:

> "with respect to the rejection pursuant to 35 U.S.C. § 102 the claims should be divided in at six separate groups of inventiveness and the erroneous nature of this rejection merits discussion with respect to each group."

Indeed, on page 14 *et seq* in the original Appeal Brief and on page 15 *et seq* in the Amended Brief, applicant provides a cogent statement regarding each of the six claim groups. Each of these groups should be

[1] The Appeal Brief is actually dated November 12, 2004, see the certificate of mailing on Applicant's original Appeal Brief; and the Amended Appeal Brief is dated January 30, 2006, see certificate of mailing.

adjudged separately for the purposes of novelty in view of the references of record. The different novel aspects of the claims termed "additional inventive features" are described on pages 3 to 6 of both versions of the Appeal Brief.

The Examiner's position regarding the claims having the differing and/or additional inventive features is, in substance, that such features are inherent in the prior art. This is in error because the claimed features are the very particular action of the compounds on several types of retinoid receptors. Claim 13 states that the compound to be used in the claimed method is an *antagonist* of retinoid receptors of the RAR γ type, does not modulate RXR receptors, and is not specific to at least one other RAR receptor subtype (namely, not specific to at least one of the RAR α and RAR β subtypes). Additional claims define the compound used in the claimed method as being not specific to RAR α (claim 14), or as not specific to RAR β (Claim 15) etc. (See the "Summary of Claimed Subject Matter" in the Appeal Brief.)

Because the cited references do not disclose the above-noted and other (recited in the claims) specific behavior towards the different types of retinoid receptors, there is a *logical inconsistency* in the Examiner's position that these characteristics are inherent in the compounds of prior art used for treating certain lung conditions. Applicant respectfully submits that if a prior art compound were to inherently have the characteristic of, for example, the compound required in Claim 14, and also the characteristics of the compound required in Claim 15, then Claims 14 and 15 would be redundant in view of Claim 13. Clearly, the recited characteristics are different as far as the RAR α and RAR β subtypes are concerned. For this

reason alone, the rejection pursuant to section 102(b) is in error when its main support is that the claimed characteristics are nowhere mentioned but are nevertheless inherent in the prior art compounds.

It also follows from the foregoing that whereas the cited prior art compounds may have beneficial effects on lung disorders, the presently claimed method does not merely reflect a discovery of the mode of action of an already known drug. Unlike the Examiner's example referring to "aspirin" (see page 10, second paragraph of the Examiner's Answer), the present invention clearly involves more than just the discovery of the mode of action of previously known compounds which allegedly "inherently" have the characteristics required in the instant claims.

Without actually testing and knowing the behavior of the compounds used in prior art methods towards the receptors recited in the instant claims, the Examiner has no basis to assert that these characteristics are inherent in the prior art methods of treating lung diseases or treating alveolar destruction.

For these reasons and the other reasons set forth in Appellant's Appeal Brief, making all claims stand or fall together regarding the issue of novelty is in serious error. Because the inherency argument used for the rejection leads to a logical inconsistency and has no basis in actual fact, the requirement that any "anticipating" reference must disclose in its four corners all features of the claims has not been met in the rejection. Therefore, the rejection pursuant to 35 U.S.C section 102(b) should be reversed, as its main support of inherency has been shown to be in error.

Argument Against Rejection Pursuant To 35 U.S.C. Section 112, First Paragraph For Failure To Comply With The Written Description Requirement

The Examiner's Answer states (see page 5) that applicant's argument is that the statute does not require clarity but merely to put Applicant's invention into the possession of the public. Applicant respectfully submits that this statement does not describe accurately Applicant's position on this issue. Applicant's position on this issue is that the written description of the instant patent application clearly describes Applicant's invention, and clearly places the claimed method in the possession of those having ordinary skill in the art pertaining to methods of treatment by retinoid and like compounds.

In the Answer to Applicant's Appeal Brief, the Examiner acknowledges that the "assay needed to determine if a candidate compound has the instantly claimed activity is routine and within the skill of the ordinary artisan." (See page 11 of the Examiner's Answer). Thus, the Examiner does not dispute that this routine assay is adequately described or referenced in the instant application. Nevertheless, the Examiner is of the position that because the application does not describe a "core compound" or a class of "core compounds," the skilled artisan would not know what compounds to test, and for this reason, the description fails to fulfill the statutory requirement of Section 112.

Applicant respectfully submits that the Examiner's position on this issue is in error. First, it is noted that the ordinary artisan in this field is well familiar with the concept and nature of "retinoids," "retinoid-like" and "retinoid-antagonist-like" compounds and is highly likely to recognize such potential biological characteristics from the chemical structural formulas of a

large class of compounds. Moreover, in view of a very substantial number of US and foreign patents, as well as of scientific publications that disclose "retinoids," "retinoid-like" and "retinoid-antagonist-like" compounds, an ordinary artisan can readily perform a literature search which would readily lead the artisan to the class of compounds to be assayed in accordance with the teachings of the present disclosure.

Still further, the passage on page 12, line 30, through page 13, line 8, of the instant specification incorporates by reference U.S. Patent Nos. 5,739,338, 5,728,846, 5,760,276 and 5,877,207, each of which describes "the synthesis of RAR ligands having antagonist and/or inverse agonist activity." These patents have general formulas of broad scope and also list numerous exemplary compounds of specific disclosed structure. The "ordinary artisan" is highly likely to consider the compounds of these references and other structurally similar compounds as potential candidates for screening in the assays clearly established in the art and referenced in the instant specification. For this reason the Examiner's assertion is in error that the instant application does not provide a "core compound" or likely candidate for the assay in search for the biological properties required by the instant claims.

Thus, the Examiner's position (see page 13 of the Answer) that it is not within the skill of the ordinary artisan to choose the compounds that should be put on the screening assays is in error. The ordinary artisan having the general high knowledge regarding "retinoids," "retinoid-like" and "retinoid-antagonist-like" compounds, coupled with the ready availability of pertinent literature and in view of the referenced examples provided in the specification, is not required to perform an "undue amount" of

experimentation while assaying compounds for the required biological activities.

It appears that in accordance with the Examiner's view, pursuant to 35 U.S.C. Section 112, a class of compounds to be used in a claimed method cannot be defined for the purposes of an enabling disclosure by biological characteristics and must be defined strictly by chemical formula. However, this requirement or result is not supported by the clear language of the statute, where it is stated:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention. (35 U.S.C. Section 112, first paragraph)

Applicant/Appellant respectfully submits that the above-quoted requirements of the statute have been fully satisfied in the instant specification with regard to identifying compounds to be used in the claimed method. The foregoing is also intended as a specific rebuttal of the Examiner's discussion of the *In re Wands* factors, which according to the Examiner, would support the rejection pursuant to 35 U.S.C. section 112, first paragraph.

In her Answer the Examiner also asserts that the specification fails to teach the application of the claimed method that is the mode of administration of the compounds used in the method and the precise nature of the diseases to be treated by the claimed method. Applicant respectfully submits that this assertion of the Examiner is also in error.

Alveolar destruction in a mammal (Claim 13) is a condition which is well known and needs no further description in a contemporary application for patent. Ordinary artisans in the healing arts know the nature and specific names of diseases which involve or result in "alveolar destruction." Moreover, the introductory section of the instant application for patent describes the nature of 'alveolar destruction" and provides examples such as brochopulmonary dysplasia (BPD) and emphysema as examples. Diseases and conditions of a mammal which benefit from increasing "the gas-exchange surface area of a mammalian lung" (Claim 21) are also well known by ordinary artisans in the healing arts, and the diseases of brochopulmonary dysplasia (BPD) and emphysema serve as examples. (See page 2, lines 5 to 14, and page 11, lines 21 to 25, of the instant specification). Thus, the specification clearly teaches to the ordinary artisan the nature of the diseases and conditions treatable by the claimed methods.

As far as modes of administration and dosages are concerned, it is well known in the art that dosage of a drug to be administered depends on multiple factors, such as the precise nature (chemical identity) of the drug, the nature of severity of the disease or condition to be treated and the nature age and condition of the subject to be treated (human or other mammal) and on the precise mode of administration. It is also well known in the art that drugs can be administered in multiple ways, which include systemic administration (for example, oral, intravenous or intraperitoneal), topical, and in case of drugs involving lung tissue as an inhalant. The instant specification discloses that these modes of administration are applicable in the claimed method (see page 12, lines 6 to line 30, of the instant specification) and describes a preferred embodiment using administration in

the form of "an inhalant as a powdered or liquid aerosol" (page 12, lines 1-15).

The art is well aware that the precise dosage and mode of administration is determined in each particular case of patient and condition by *routine* experimentation and experience. Such routine experimentation is not considered in violation of the enabling and best mode requirements of 35 U.S.C. Section 112.

CONCLUSION

In light of the foregoing, the rejection of Claim 13 – 28 pursuant to 35 U.S.C. Sections 102(b) and 112, first paragraph is in error. The Examiner's Answer has not refuted successfully the reasons for reversal set forth in Appellant's Brief on Appeal, and the rejections should be reversed.

Respectfully submitted

Date: October 27, 2006

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